UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,110	12/02/2003	Gary Searle	03-062-GS	4782

7590 09/11/2007

LAMBERT & ASSOCIATES
SUITE 200
92 STATE STREET
BOSTON, MA 02109

EXAMINER	
DAWSON, GLENN K	
ART UNIT	**PAPER NUMBER**
3731	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

C

EXAMINER	
ART UNIT	PAPER
	20070830

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Please see the attached Examiner's Answer.

Glenn K Dawson
Primary Examiner
Art Unit: 3731

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/726,110
Filing Date: December 02, 2003
Appellant(s): SEARLE, GARY

Adam J. Bruno
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 05-16-2007 appealing from the Office action mailed 01-20-2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 2,8,15,24-75 and 78-105 have been withdrawn.

Claims 1,3-7,9-14,16-23,76 and 77 are finally rejected.

This appeal involves claims 1,3-7,9-14,16-23,76 and 77.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,517,575	yang	02-2003
6,458,152	khosravi	10-2002
6,042,046	martin	03-2000
5,824,046	smith	10-1998
6,428,571	lentz	08-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 76 and 77 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,517,575 to Yang.

Yang discloses a self-expanding stent that is in the form of a rolled sheet. The rolled sheet has many layers, including a layer of expandable filler material. Yang explains that the expandable filler material swells upon absorbing water when placed in a body lumen (column 2, lines 45-50 and column 4, lines 60-65).

Claim Rejections - 35 USC § 103
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,4,5,9-14, 16 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,458,152 to Khosravi et al. in view of Yang. Khosravi discloses a rolled sheet self-expanding stent that includes layers of

different materials. One layer, or "stent body" is formed from a shape memory metal (column 6, lines 40-45). A polymeric layer is disposed on the interior of the stent body and can be in the form of several layers (column 3, lines 35-45). An additional polymer layer can be disposed on the exterior of the stent to form a "barrier film", and it can be porous (column 5, lines 35-50). An alternate barrier film encapsulating the stent is disclosed (column 7, line 61 through column 8, line 5). The stent can also include a coating of heparin (column 8, lines 63-65). A balloon catheter can be used for implantation (column 9, line 36 and Figure 5B).

Khosravi fails to include an expandable filler material, but does state that the inner polymer layer can be formed as several layers (column 3, lines 35-45). Khosravi also requires a balloon catheter for aiding in the expansion of the prosthesis. As explained above, Yang also discloses a rolled sheet self-expanding vascular prosthesis. Yang teaches that this type of prosthesis should include an expandable filler material bonded to another thin sheet. The expandable material aids in the self-expansion of the stent, as it causes the sheet to unroll and expand as the material swells when in contact with water in the body lumen. Yang also explains that other types of layers, including metal, may be formed with the rolled sheet stent (column 2, line 65 through column 3, line 3). These statements provide motivation to combine the Yang and Khosravi devices. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the multilayered polymer portion of the Khosravi stent as an expandable filler material bonded to a thin sheet, as Yang teaches that this combination of materials aids in the self-expansion of a rolled sheet stent. The expanding material may be capable of replacing the use of a balloon catheter.
Yang states that the expandable layer may be biodegradable and gives many examples of materials that can form the expandable polymer layer in column 3. The expandable layer (20) is disposed on a thin sheet of material that can be polymeric or metallic (10)(column 2, lines 55-60). Yang explains that other types of layers, including metal, may be formed with the rolled sheet stent (column 2, line 65 through column 3, line 3).

Claims 10 and 13 only include limitations pertaining to the method by which the product is made. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. Therefore, the limitations of claims 10 and

13 were not given patentable weight.

Claims 19-21 only pertain to intended use of the device. The only requirement here is that the prior art stent be capable of performing these functions. Since the Yang stent is capable of being used with another stent and in procedures pertaining to animals or humans, it meets the limitations of claims 19-21.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of US Patent No. 6,042,605 to Martin et al.

The modified Khosravi device fails to form the stent body from a cobalt-chrome alloy, or Elgiloy. Khosravi does state that the stent body can be formed of nitinol or stainless steel (column 6, lines 41-45). Martin discloses a stent body disposed over a polymer graft. Martin teaches that Elgiloy is a suitable material to use as a substitute for nitinol, as it is highly resilient (column 11, lines 5-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Elgiloy for nitinol for the material of the stent body of the modified Khosravi stent, as Martin teaches that Elgiloy has good mechanical properties for forming stents.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of US Patent No. 6,428,571 to Lentz et al.

As explained above, Yang discloses many different materials for forming the expandable layer in column 7. Among those materials are gelatin, collagen, albumin, and starch. Lentz teaches that casein is another natural material equivalent to gelatin, collagen, albumin, and starch for forming expandable polymer layers (column 8, lines 38-49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include casein in the expandable filler material of the modified Khosravi device, as Lentz teaches that casein is simply an alternate natural material for forming expandable polymer layers.

Claim7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of US Patent No. 5,824,046 to Smith et al.

Khosravi states that the outer polymer layer, or "barrier film", can be formed of graft materials, such as PTFE, polyester, or urethane (column 7, lines 11 and 64). Smith discloses a stent with a polymeric outer layer. Smith teaches that polypropylene is a suitable Substitute for PTFE, polyurethane, and polyester for forming the barrier film (column 7, lines 32-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the barrier film of the modified Khosravi device of polypropylene, as Smith teaches that this material is suitable for forming a barrier film for a stent.

(10) Response to Argument

Applicant argues that the 102 rejection of claims 76 and 77 is flawed because Yang does not disclose a device which is used for the same purpose (occlusion) as the applicant. Neither of these claims is limited to an occlusion device. All of the recited structural limitations of the claims are met. It is not necessary for anticipation that the prior art device be disclosed as being used for the same purpose as the applicant's invention. As long as all of the structural limitations are met and the prior art is capable of performing any "claimed" functions or intended uses, then the prior art anticipates the claims. In this case, the structural requirements are met, and no functions or intended uses are claimed which the prior art cannot perform. The stent of the prior art will expand from a smaller orientation to a larger orientation when subjected to fluid in the body. This would allow the device to dilate a vessel. Applicant argues that the materials and/or specific structure which undergo expansion are different in the prior art than those "disclosed" by the applicant. Applicant

here is arguing limitations which are not in the rejected claims. On page 15 of the brief, applicant argues that the instant invention is not a natural progression of Yang's invention... this is irrelevant to the issue of anticipation; as is the premise that a substitution of applicant's materials into Yang's design would not permit Yang's device to function similarly.

Applicant outlines differences between the structures/materials of Yang and the present invention. Again, since none of these are found in the claims, the differences are irrelevant.

Applicant attempts to rebut the argument that the limitations relied upon for non-anticipation are not in the claims by stating "Claim 76 recites in part that the natural state of the element, the "natural or unrestrained state is slightly larger than the intended inner diameter of the vessel". This shows that the element is not only intended to result in occlusion, but that the element is *structurally* capable of achieving occlusion because of the physical characteristics of the element , i.e. its structure." This statement is not understood. The examiner can not see why anyone reading this sentence of the claim would come to the necessary conclusion (inherent) that such provides evidence that the device is intended for occlusion.

It should also be noted that claims 76 and 77 are drawn to a device capable of ***dilating*** or occluding a vessel.

With respect to the 103 obviousness rejections, Applicant argues each of the base reference and the teaching references individually. Pointing out individual differences between each of the teaching references and the present invention does not rebut obviousness of the claimed invention based on a combination of references. Additionally, as above, Applicant in each instance argues limitations not found in any of the rejected claims.

Applicant argues that Khosravi's device is used differently than the present invention. However, a stent graft is used to plug or cover a hole or aneurysm in some instances and this would be a form of occlusion. Additionally, again none of the relied upon differences of structure or intended use can be found in any of the rejected claims.

On page 21 of the brief, Applicant refers to invention #2 and Invention #4. These references are not understood.

The different type of winding of the layers on page 23 is again not found in the claims and therefore irrelevant.

It is irrelevant if applicant's expandable materials are different, as long as the prior art has some expandable materials, as the claims do not define a particular material or its placement in the overall structure which is not found in the prior art. It is irrelevant if the structure of the prior art provides a different

encapsulating structure than the applicant as long as some encapsulation is present which reads on the claimed encapsulation.

In summary, applicant has failed to identify any "claimed" structure which is not found in the prior art references. Applicant has also failed to identify any claimed function which the prior art is unable to perform. The applicant has also failed to state how any references used in an obviousness rejection could not or should not be combined.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Glenn K Dawson

GLENN K. DAWSON
PRIMARY EXAMINER

Glenn K. Dawson

Conferees:

***

(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER

Thomas Barrett
TC 3700 TQ45